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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/269,711 04/05/99 SAKAI

T 1/F3511PTUS

EXAMINER

HM12/0207

WENDEROTH LIND & PONACK
2033 K STREET NW
SUITE 800
WASHINGTON DC 20006

MANUSCRIPT
ART UNIT

PAPER NUMBER

1617
DATE MAILED:

02/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/269,711

Applicant(s)

SAKAI ET AL.

Examiner

Shengjun Wang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Receipt of amendments, Declaration by Nobuaki Kazahaya and the translated copies of JP 356416 and JP 311224 submitted November 27, 2000 is acknowledged.

Applicants' amendments and remarks are persuasive to overcome the amendment abjection and claim rejections under 35 U.S.C. 112 set forth in the prior office action.

Claim Objection

1. Claim 40 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim is a dependent claim of a cancelled claim.

Claim Rejections 35 U.S.C. § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed inventions exclude the presence of any other moieties in the glycerol lipid or glycerolglycolipid. This is not supported by the original disclosure.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 39- 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 39 recites a glycerolipid consisting of glycerol and fatty acid and glycerolglycolipid consisting of fatty acid, sugar and glycerol, it is unclear that if the glycerolipid herein is defined as "consisting of glycerol and fatty acid," and the glycerolglycolipid is defined as "fatty acid, sugar and glycerol," or the components of the glycerolipid compound are consisting of glycerol moiety and fatty acid moiety," and the components of compound glycerolglycolipid are consisting of the moieties of fatty acid, sugar and glycerol. The claim is indefinite as to the chemical compounds encompassed by the glycerolipid or glycerolglycolipid thereby.

7. Claim 40 recited a "apoptosis inducing agent of claim 21," since claim 21 was cancelled, it is not clear what the apoptosis inducing agent is. The claim is indefinite as to the apoptosis inducing agent encompassed thereby.

Claim Rejections 35 U.S.C. - 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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9. Claims 22-24, 26 –27 and 37 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Winget (US Patent No. 5,767,095).

Winget teaches a composition comprising glyceroglycolipid. See, particularly, the abstract. The glyceroglycolipid is obtained by extracting alga with an organic solvent followed by purification on normal phase chromatography. See, particularly, columns 10-12. Winget also teaches that purity of the glyceroglycolipid is important, i.e., the glyceroglycolipid should be free from other compounds, e.g., phospholipid. See column 1, lines 29-40, particularly, column 1, line 32.

10. Claims 22-24, 26 –27 and 37 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Winget (US Patent No. 5,620,962).

Winget teaches a composition comprising glyceroglycolipid. See, particularly, the abstract. The glyceroglycolipid is obtained by extracting alga with an organic solvent followed by purification on normal phase chromatography. See, particularly, columns 10-12. Winget also teaches that purity of the glyceroglycolipid is important, i.e., the glyceroglycolipid should be free from other compounds, e.g., phospholipid. See column 1, lines 27-40, particularly, column 1, line 30.

Claim Rejections 35 U.S.C – 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 25, 28-36 and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over both Winget (US Patent No. 5,767,095) and Yazawa et al. (AB) JPO abstract provided herewith, in view of Wright et al. (CAPLUS Abstract, 1980:74554) and Nelson ("Isolation and Purification of lipids from Biological Matrices," in Analysis of Fats, Oil and lipoproteins, Edited by Edward G. Perkins, 1993).

Winget teaches a composition comprising glyceroglycolipid. See, particularly, the abstract. The glyceroglycolipid is obtained by extracting alga with an organic solvent followed by purification on normal phase chromatography. See, particularly, columns 10-12. Winget further teaches that glyceroglycolipid is present in many food products, e.g., lettuce, broccoli, wheat, etc. See column 1, 19-22. Yazawa et al. teach a composition comprising glyceroglycolipids as the active components for treating or preventing cancer.

The primary references do not teach expressly the employment of glyceroglycolipid in food and beverage products. The primary references do not teach the employment of acid and/or base in the process of making the glyceroglycolipid.

However, Wright et al. teach that tea comprises glyceroglycolipid, suggesting that glyceroglycolipid may be consumed in a beverage. See the abstract. Nelson teaches that acid treatment of materials containing lipid is a well-known technique for lipid separation and purification. See page 45.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ glyceroglycolipid in food or beverage products and to employ acid treatment in the process of making the glyceroglycolipid.

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A person of ordinary skill in the art would have been motivated to employ glyceroglycolipid in food or beverage products because glyceroglycolipids are known to be useful for treating or preventing cancer and are known to be present in many food and beverage products. The employment of glyceroglycolipid in food or beverage products is reasonably expected to be beneficial for maintaining health. Furthermore, the employment of acid/base treatment in the process of making the glyceroglycolipid is seen to be obvious since the separation/purification of prior art glyceroglycolipids would be expected to increase the concentration of the active glyceroglycolipids in the instant composition and is considered within the skill of artisan because acid treatment is a well known technique for purification and separation. Note that intended use "apoptosis induction" does not further limit claims drawn to a composition. See, e.g., In re Hack 114 USPQ 161. Regarding the newly added claim 39 which limits the lipid to consisting of glycerol and fatty acid or glycerol, sugar and fatty acid, it is seen to be obvious over the cited art since the cited art teach broadly that the usefulness if glycerolipid or glycerolglycolipid. Any glycerolipid or glycerolglycolipid would have been reasonably expected to be similarly useful, absent evidence to the contrary.

13. Claims 25, 28-36 and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over both Winget (US Patent No. 5,620,962) and Yazawa et al. (AB) JPO abstract provided herewith, in view of Wright et al. (CAPLUS Abstract, 1980:74554) and Nelson ("Isolation and Purification of lipids from Biological Matrices," in Analysis of Fats, Oil and lipoproteins, Edited by Edward G. Perkins, 1993) for reason as discussed above.

In response to applicants' remarks regarding the validity of Winget reference as a prior art references, note that filing date of U.S. parent application can be used as the 35 U.S.C. 102

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(e) date if it support the claims of the issued child. See, MPEP 2136.03. Winget ('095) is a continuation of Ser. No. 484,832 filed Jun.7, 1995. Therefore, Winget reference is a valid prior art reference.

14. Applicant's amendment and the perfection of the priority data necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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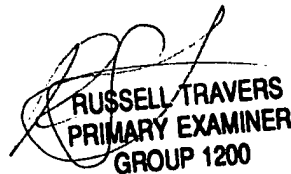
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Shengjun Wang

AU 1617

January 31, 2001



RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200